

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
5 February 2004 (05.02.2004)

PCT

(10) International Publication Number
WO 2004/011035 A3

- (51) International Patent Classification⁷: **A61K 49/00**
- (21) International Application Number: **PCT/IL2003/000552**
- (22) International Filing Date: **3 July 2003 (03.07.2003)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
150906 25 July 2002 (25.07.2002) **IL**
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- (81) Designated States (*national*): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.**
- (84) Designated States (*regional*): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).**
- Published:
— *with international search report*
— *with amended claims*
- (88) Date of publication of the international search report: **18 March 2004**
- Date of publication of the amended claims: **29 April 2004**
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **BIO-DEGRADABLE MICROSPHERES FOR DIAGNOSING GASTROESOPHAGAL REFLUX**

(57) Abstract: The invention provides a diagnostic composition for detecting both aspiration and gastroesophageal reflux comprising bio-degradable microspheres having a diameter of about 0.1-10 microns.



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AMENDED CLAIMS

[received by the International Bureau on 10 March 2004 (10.03.04);
original claims 1-8 replaced by amended claims 1-7;
(1 page)]

WHAT IS CLAIMED IS:

1. A diagnostic composition for detecting pulmonary aspiration comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns wherein said polymeric microspheres are formed from polymeric materials selected from the group consisting of polyesters, polyphosphate esters, polyphosphazenes, polyorthoesters, polyanhydrides, polycarbonates and polyamides.

2. A diagnostic composition according to claim 1 wherein said bio-degradable polymeric microspheres have a diameter of about 1 - 4 microns.

3. A diagnostic composition according to claim 1 wherein said polyesters are selected from the group consisting of homopolymers and copolymers of lactic acid, glycolic acid, mandelic acid, caprolactone, α -hydroxy acids, lactides and glycolides.

4. A diagnostic composition according to claim 1 comprising bio-degradable microspheres of polylactic acid.

5. A food product in combination with a diagnostic composition for detecting pulmonary aspiration said composition comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns.

6. The use of bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns for the manufacture of a diagnostic composition for detecting pulmonary aspiration.

7. A diagnostic method for detecting pulmonary aspiration comprising providing a diagnostic composition comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns for oral administration in combination with food, wherein said microspheres are identifiable within the alveolar macrophages obtained by bronchoalveolar lavage.